IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH,	)	
Plaintiff,	)	
	)	Civil Action No. 06-222-JJF
v.	)	
	)	**REDACTED**
IMPAX LABORATORIES, INC.,	)	
Defendant,	)	

WYETH'S ANSWERING BRIEF IN OPPOSITION TO IMPAX'S MOTION TO COMPEL DEPOSITION PURSUANT TO FED. R. CIV. P. 30(b)(6)

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I. NATURE AND STAGE OF THE PROCEEDINGS

This is not Impax's first attempt at a sweeping Rule 30(b)(6) deposition notice. On January 22, 2007, Impax served on Wyeth a First Amended Notice of Deposition pursuant to Rule 30(b)(6) (the "First Amended Notice," D.I. 82), which contained 34 overbroad topics that touched upon virtually every allegation Impax made in this ANDA litigation. Wyeth objected that this First Amended Notice placed an undue burden on Wyeth, in part because it did not set forth the topics with reasonable particularity.[1] Although Wyeth offered to work with Impax to craft more reasonable topics, those negotiations failed and Wyeth was forced to seek a Protective Order from the Court. (D.I. 81). On March 2, 2007, the Court granted Wyeth's motion, acknowledging that Impax's Notice had "correctly been attacked as overly broad." [D.I. 106, March 2, 2007 Hearing Tr. at 15].

Undaunted, no less than one week later, Impax repackaged its prior notice into a Second Amended Notice of Deposition Pursuant to Fed.R.Civ.P. 30(b)(6) (the "Second Amended Notice," D.I. 110). The Second Amended Notice contains 32 topics -- only two less than the First Amended Notice that the Court found to be overly broad. For the reasons discussed in detail below, Impax's Second Amended Notice suffers from the same defects that resulted in the Court concluding that the first notice was overly broad. And for those same reasons, Impax's motion to compel should be denied.

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[1] Wyeth also objected to a number of Impax's topics as improperly seeking testimony on legal contentions and other potentially privileged issues that courts have recognized as improper for Rule 30(b)(6) depositions, as set forth more fully below. The Court did not need to address these objections in its prior ruling in light of its finding that the First Amended Notice was overbroad.

II. SUMMARY OF ARGUMENT

Little has changed since March 2, 2007, when the Court granted Wyeth's motion for a Protective Order against Impax's virtually unbounded First Amended Notice. Although Impax urges that its Second Amended Notice "narrow[ed]" the Rule 30(b)(6) deposition topics [Impax Br., D.I. 113, at 1], a careful review of the Notice demonstrates that it has not. Indeed, as set forth below, Impax has actually ***broadened*** a number of the topics, adding to the undue burden that Wyeth faced previously with Impax's First Amended Notice.

Impax's assertion that it has tailored its notice to "eight general topics" is misleading at best. Not only are these "eight general topics" littered with argumentative and unsubstantiated allegations, they also attempt to mask the fact that Impax's Second Amended Notice still actually contains 32 separate topics of essentially the same scope (or in some cases broader scope) as those of Impax's First Amended Notice. Indeed, Impax concedes that potentially hundreds of individuals would need to be queried in order to respond. [Impax Br., D.I. 113, at 1]. In short, Impax's Second Amended Notice does nothing to alleviate the undue burden the Court recognized Wyeth would face if forced to educate Rule 30(b)(6) designees on nearly every fact touching on virtually every issue in this case.

By way of example, subpart (a) of Topic 26 seeks testimony on FACTS evidencing the Integrated Safety Summary of Wyeth's NDA No. 20-699 (including any amendments through July 2002). This sub-part alone is overbroad in that the Integrated Safety Summary is a summary document submitted to the FDA that collates and analyzes data from all of Wyeth's clinical studies for extended release venlafaxine hydrochloride that were conducted or commenced as of its submission to the FDA. The Integrated

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Safety Summary covers, *inter alia*, :

drug-disease interactions. Impax estimates that questions on all four subparts of Topic 26 will take 3 hours. [Ex. 2 at 2]. Surely, for Impax to have estimated only 3 hours of questioning on such a broad topic, it must have a more particularized understanding of the information it truly seeks. Impax certainly did not consider the enormous burden that Wyeth would face in attempting to prepare a witness to testify on every aspect of just this one document alone.

Moreover, although Impax has provided some loose time estimates for the various topics to make its Second Amended Notice seem less burdensome, Impax is still not even certain of the amount of time its topics will take. As noted in Impax's letter of March 9, 2007, where it set forth its estimated times (4 deposition days), Impax leaves itself the option of unilaterally altering those times at the deposition. [*See* Impax Br., D.I. 113, at 5]. More importantly, the number of days Impax estimates *to take* the deposition has nothing to do with the several weeks, at minimum, it would take Wyeth to prepare designees to testify. The reality is that Impax still expects Wyeth to wade through the 32 overbroad topics and anticipate all of the potential questions that may be posed to one or

more Rule 30(b)(6) witnesses for four days on virtually every issue in the case. Indeed, that was acknowledged at the March 2, 2007 Hearing:

> MR. KASSIBIAN: I think in most cases, as to most topics we're looking for evidence that we would submit at trial.
>
> THE COURT: So this is -- you expect to get substantive evidence out of this deposition on all those topics? And can you --
>
> MR. KASSIBIAN: On most, I think.
>
> ***
>
> MR. LEWRIS: Your honor, this could go on for many, many days. What Mr. Kassibian effectively said, Your Honor, is what I said at the outset, what they want to do is collect all their evidence for trial through the first 30(b)6 and only deposition in the case.
>
> THE COURT: That's what it sounds like.

[D.I. 106, March 2, 2007 Hearing Tr. at 11, 13].

Impax continues to adhere to an improper legal standard, arguing that the only constraint on its Rule 30(b)(6) Notice is that it seek "relevant" information, without even considering the impossible burden placed on Wyeth to attempt to prepare witnesses on such unbounded topics, including those that improperly implicate privilege concerns and seek contention discovery. As was the case with the First Amended Notice, Impax should not be permitted to skirt the Rule 30(b)(6) particularity requirement, and unduly burden Wyeth with having to prepare witnesses to review over one million pages of documents and other evidence spanning many years, and to then lay out every exacting detail of its case in a "four-day" deposition. Such a burden is plainly undue and is not the proper role of a Rule 30(b)(6) deposition.

III. STATEMENT OF FACTS

As with the previous briefing on the issue, Impax misstates the facts at nearly every turn. In one of the few statements in Impax's brief that is grounded in reality, this is a Hatch-Waxman patent litigation between a large pharmaceutical company, Wyeth, and a generic drug manufacturer, Impax. As Impax correctly notes, the "stakes here are very high" because the branded drug that is covered by the patents-in-suit, Effexor XR, has been a huge commercial success. That success stems from the recognition by doctors and patients that Effexor XR is extremely effective in treating, among other things, depression and anxiety. And that success further stems from the huge investment in time and effort Wyeth spent in the development and testing process that ultimately led to FDA approval of Effexor XR.

Impax expended none of the time and resources that were necessary to achieve that success. Instead, Impax seeks to reap its reward by copying Wyeth's patented invention and hurling a never-ending barrage of baseless allegations against Wyeth, hoping that at least something will stick. Having served voluminous document requests directed to virtually every aspect of Effexor XR and the patents-in-suit, and having raised virtually every conceivable attack against those patents, Impax now complains that it must have its Rule 30(b)(6) deposition to "break through the log jam of the millions of documents and hundreds of potential deponents so that this case can be manageably tried and more importantly to simplify the issues for trial." [Impax Br., D.I. 113, at 1]. What Impax seeks is not to simplify, however, but to require Wyeth to pre-try its case before Impax on the basis that Wyeth has the resources to do so because it is a large and successful company. Indeed, Impax acknowledges that this case "involves millions of documents and literally potentially hundreds of individuals who might have relevant

knowledge regarding the evolution of this time-release technology, the patents and circumstances regarding this action ... spanning a period of over 15 years." [Impax Br., D.I. 113, at 1]. What Impax thus seeks to do is shift the burden of preparing its case to Wyeth. The Federal Rules protect all parties, regardless of size, from discovery that constitutes an "undue burden."[2]

Impax now contends that because Wyeth responded to Impax's broad discovery requests, and also produced voluminous fact and expert materials from the Teva case, Wyeth somehow has "all of the information pertinent" to the testimony Impax seeks through its overbroad Second Amended Notice. [*Id.* at 2]. First, as Impax well knows, the issues in the Teva case were not as broad as the topics of Impax's Second Amended Notice. Further, just because Wyeth produced these materials does not mean, however, that Wyeth would not be unduly burdened by having to prepare witnesses to review them, and be prepared to testify on any and every conceivable question that Impax might ask over a four-day period on virtually every issue in this litigation.

Impax apparently does not want to be troubled with having to review all of the materials it requested. Instead, Impax seeks to do the same as it did with the development of its extended release venlafaxine -- let Wyeth do the work by forcing it to select designees to first guess as to what Impax's Second Amended Rule 30(b)(6) Notice actually seeks, to then review and synthesize all of the materials Wyeth has produced in

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[2] Despite Wyeth's repeated urgings, Impax still had taken no personal depositions of Wyeth employees as of the March 2, 2007 Hearing. Not until after the Court granted Wyeth's Motion for a Protective Order on the overbroad First Amended Rule 30(b)(6) Notice did Impax notice the personal depositions of two of Wyeth's inventors, who Wyeth has indicated are available for deposition on April 17th and 19th.

this litigation, and to finally present its entire case to Impax in a single, tidy, "four-day" Rule 30(b)(6) deposition. Rule 30(b)(6) was never intended to be used in such a manner.

IV. ARGUMENT

A. Impax Continues To Apply The Incorrect Legal Standard And Does Not Address The Undue Burden Wyeth Would Face In Attempting To Comply With The Second Amended Notice

Impax continues to apply the incorrect legal standard by arguing, in essence, that because the noticed topics potentially touch upon some "relevant" information, the requirement of Rule 30(b)(6) that the topics be described with "particularity" is somehow jettisoned. Fed. R. Civ. P. 30(b)(6) unambiguously requires that a notice must define the requested subject matter "with reasonable particularity," however, and Fed. R. Civ. P. 26 does not eviscerate that requirement. *Carpenter Tech. Corp v. Armco, Inc.*, 1990 U.S. Dist. LEXIS 5538, *8, *11-12 (E.D. Pa. May 7, 1990)(striking Rule 30(b)(6) testimony and noting that scope of discovery is "not without bounds."); *Reed v. Bennett*, 193 F.R.D. 689, 692 (D. Kan. 2000)("Where, as here, the [party] cannot identify the outer limits of the areas of inquiry noticed, compliant designation [of a witness] is not feasible.").

Further, contrary to Impax's assertions, the topics in its Second Amended Notice are not "carefully targeted to discrete subject areas." [Impax Br. at 5]. In fact, as set forth below, the 32 topics of Impax's Second Amended Notice are, for the most part, merely a rearrangement of the 34 topics of Impax's First Amended Notice that the Court found was overbroad. That Impax attempts rearrange the topics under "eight general topics" does not alter the fact that the overall number and scope of the topics is largely

unchanged, and in some cases actually broadened.[3] "[T]he [Federal] Rules . . . preclude proponents of discovery from wielding the discovery process as a club by propounding requests compelling the recipient to assume an excessive burden." *SmithKline Beecham Corp. v. Apotex Corp.*, No. 98 C 3952, 2000 WL 116082, *9 (N.D. Ill. Jan. 24, 2000); *In re Independent Service Organizations Antitrust Litigation*, 168 F.R.D. 651, 654 (D. Kan. 1996)("Even under the present-day liberal discovery rules, Xerox is not required to have counsel 'marshal all of its factual proof' and prepare a witness to be able to testify on a given defense or counterclaim.")

Impax's Second Amended Notice continues to place an impossible burden on Wyeth to, in effect, prepare "super human," omniscient witnesses to testify on all of Wyeth's historical facts, theories, and contentions for virtually every issue in this case. [Ex. 1, Kent Sinclair and Roger P. Fendrich, *Discovering Corporate Knowledge and Contentions: Rethinking Rule 30(b)(6) and Alternative Mechanisms*, 50 Alabama L. Rev. 651, 704 (1999)]. The requirement for "reasonable particularity" exists in part because the potential for discovery abuse is particularly high in the Rule 30(b)(6) context. In addition to the burden of having to guess at the scope of improperly overbroad topics, there is also the specter of unfair preclusion of evidence. Because the Rule 30(b)(6) designee testifies on behalf of the party, rather than in a personal capacity, if the designee cannot adequately respond to unanticipated questions, the party may well be confronted with a challenge if it later attempts to present evidence regarding that same subject matter. *Id.* at 701-702.

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[3] Impax also makes much of the fact that it allegedly spent a week revising its notice. [Impax Br., D.I. 113, at 4]. That it repackaged its notice, however, does nothing to alleviate the burden that would be placed on Wyeth.

Impax fails to provide a compelling reason for burdening Wyeth with a "four-day" deposition on nearly every issue in the case without providing more particularized topics. Moreover, Impax's assertion that it requires this Rule 30(b)(6) discovery because the facts are "completely within Wyeth's control," [Impax Br., D.I. 113, at 5] is neither accurate nor a basis for imposing an undue burden on Wyeth. Wyeth has provided Impax with voluminous discovery and Wyeth has never refused to make fact witnesses available for deposition. Indeed, the personal depositions of inventors are currently scheduled to commence on April 17th.

As a result of the breadth of Impax's Second Amended Notice, Wyeth must prepare multiple witnesses for what Impax guesses to be four days of deposition. In its March 9, 2007 letter to Wyeth forwarding the Second Amended Notice, Impax states that this guesstimate assumes, among other things, that "there is adequate preparation of the deponent(s)." [Ex. 2, March 9, 2007 letter at 1]. However, Impax dismisses the extent of that preparation, stating that Wyeth was prepared "to go to trial on these very issues in the Teva case, and thus already expended the resources to gather this information in litigating that case." [Impax Br. at 2-3]. Although there may be overlap between some of the issues in this case and the Teva case, that does not reduce the burden on Wyeth of preparing witnesses to address the laundry list of 32 overbroad topics set forth in Impax's Second Amended Notice. Second, Wyeth already provided to Impax all the Rule 30(b)(6) depositions of Wyeth and Wyeth's responses to contention interrogatories in the Teva case, as well as Wyeth's pretrial submissions. If, as Impax suggests, Wyeth already has done all the work, then it is also true that Impax has all the answers from the Teva

case. However, as Impax well knows, its massive Rule 30(b)(6) notice goes far beyond the scope of the Rule 30(b)(6) depositions of Wyeth in the Teva case.

The four days of estimated deposition time does not come close to addressing the burden on Wyeth. In its Brief, Impax says that following the March 2nd hearing, "counsel for Impax, including local counsel, spent a week revising Impax's Notice to comply with the Court's guidelines." [Impax Br. at 4]. The week that Impax spent just preparing its sweeping Second Amended Notice will not match the several weeks, at minimum, it will take Wyeth to prepare multiple witnesses to address Impax's laundry list of topics, Simply put, there is no basis for placing such an undue burden on Wyeth. That Impax chose not to review the documents and other discovery that Wyeth provided pursuant to *Impax's* requests, or to depose fact witnesses on those documents, does not provide a legitimate basis for placing such a burden on Wyeth.

B. The Second Amended Notice Actually Contains 32 Topics Nearly Identical To, Or In Some Cases Broader Than, The 34 Topics From Its Rejected First Amended Notice

1. Impax "General Topic I" Actually Consists of *Two* Topics That Are Overbroad, Seek Wyeth's Legal Contentions And/Or Seek Information Protected By The Attorney-Client Privilege

Impax's "general topic I" actually consists of two distinct topics, Topics 1 and 2, each of which is objectionable for a variety of reasons.[4]

On its face, the plain language of Topic 1 demonstrates its sheer overbreadth. Topic 1 seeks:

> FACTS supporting or evidencing WYETH's conception and reduction to practice of the alleged invention(s) claimed in each of

[4] These Topics are of essentially the same scope as Topics 1 and 2 of the First Amended Notice.

> the asserted claims of the PATENTS IN SUIT and claim 1 of U.S. Patent No. 6,274,171 B1. (This should be interpreted to include the identity of documents and witnesses as well as when and where those conceptions and reductions to practice took place, who was present and/or participated, what transpired, what DOCUMENTS were authored contemporaneously or near contemporaneously to record what transpired, and the significance of conception and reduction to practice milestones).

Impax expects Wyeth to educate a witness to provide Rule 30(b)(6) testimony as to any and every person that was "present and/or participated" in any aspect of the conception and reduction to practice of the numerous asserted claims, what transpired on each of these occasions, and identify all documents authored either contemporaneously or "near contemporaneously" with those occasions, without any consideration of the nature or importance of that "participation" or documentation. Impax does not further define the information it seeks through this topic, and by its plain language, it clearly calls for the identity of people and documents that may be only marginally relevant. As Wyeth has maintained throughout this litigation, personal depositions which explore the history of the research and development efforts leading to the claimed subject matter is the most efficient and useful method for ascertaining who was involved in conception and reduction to practice of the asserted claims, and what documentation records exist for those activities. Moreover, because the deposition transcripts from the Teva litigation for the named inventors have already been produced to Impax, much of the information sought has already been provided to Impax.

Further, conception and reduction to practice are issues of *law*. *Hybritech Inc. v. Moncolonal Antibodies, Inc.*, 802 F.2d 1367, 1376 (Fed. Cir. 1986)("Reduction to practice, and conception as well, is a legal determination..."). And despite Impax's claims that it now seeks only "FACTS" related to those issues, "inserting of the word

'facts' doesn't make [a deposition topic] less of an effort to get at what is essentially the legal position of the party ...." [Ex. 3, *Pharmacia & Upjohn Co. v. Sicor, Inc.*, C.A. No. 04-883 (KAJ) (Tr. at 36) (D. Del. Oct. 11, 2005)]. Indeed, Topic 1 even expressly asks for Wyeth's contentions in that it seeks testimony on "the significance of conception and reduction to practice milestones." When those facts are so inextricably intertwined with the legal contentions they support, this Court and others have held that discovery of such issues should be conducted using other methods, such as through contention interrogatories.[5] *Heron v. Potter*, No. Civ. A. 03-313-JJF, 2006 WL 3703693 at *1 (D. Del. Oct. 23, 2006); *McCormick-Morgan, Inc. v. Teledyne Indus., Inc.*, 134 F.R.D. 275, 287 (N.D. Cal. 1991), *rev'd on other grounds*, 765 F. Supp. 611 (N.D. Cal. 1991); *see also* Ex. 4, *McKesson Information Solutions LLC v. The TriZetto Group, Inc.*, C.A. No. 04-01258 (SLR) (Tr. at 21) (D. Del. Aug. 2, 2005)("I have never thought contention Interrogatories are appropriately responded to via 30(b)(6) depositions.... So if you ask for depositions concerning the basis for a defense, that is a contention interrogatory."). Impax's Topic 1 is "so broadly worded, it can't help but really be a circumstance where somebody is asked to know every fact pertaining to every contention and that's a bit much to put on a deponent." [Ex. 3, *Pharmacia*, (Tr. at 37)].

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, the extent Impax now seeks additional non-privileged factual information regarding these issues, such as "what actually transpired, who was present, what was discussed" [Impax Br., D.I. 113, at 17], Impax can obtain that information through personal depositions of the persons Wyeth identified in its responses to those interrogatories.

Topic 2 of Impax's Second Amended Notice similarly seeks:

> Non-privileged information, unless Wyeth knowingly waives privilege, regarding all invention records CONCERNING the asserted claims of the PATENTS IN SUIT and claim 1 of U.S. Patent No. 6,274,171 B1. (This includes without limitation when such records were authored, by whom, pursuant to whose instruction or pursuant to what policy (if any), to whom they were provided, how were they provided, when they were provided, what was the purpose of providing the invention records to such person(s), whether oral communications were contemporaneously or near contemporaneously made with the provision of the records, and where such records are usually kept in the ordinary course of business.)

As Wyeth has noted, the Federal Circuit has held that invention records are privileged. *In re Spalding Sports Worldwide, Inc.*, 203 F.3d 800, 806 (Fed. Cir. 2000). Although Impax tries to couch this topic as seeking "non-privileged information," much of the information it seeks is in fact privileged. For example, information regarding "pursuant to whose instruction or pursuant to what policy" the invention records were made, "the purpose of providing the invention records to such person(s)," and "oral communications" made contemporaneously or near contemporaneously, all implicate communications protected by the attorney-client privilege. The burden involved in attempting to extricate the "non-privileged" information from the privileged is unduly burdensome and courts have recognized that Rule 30(b)(6) testimony is not the best mechanism for such discovery. *Hercules Inc. v. Exxon Corp.*, 434 F. Supp. 136, 144 (D. Del. 1977).

Moreover, as Wyeth noted in its Reply in support of its Motion For a Protective Order, much of the non-privileged information Impax seeks already has been produced. [Wyeth Reply Br., D.I. 97 at 6]. Specifically, Wyeth has produced the deposition testimony of one of its inventors from the Teva case addressing:

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For the above reasons, Topics 1 and 2 are overly broad and inappropriate Rule 30(b)(6) topics.

2. Impax's "General Topic II" Actually Consists of *Two* Overbroad Topics

Impax's "general topic II" actually consists of Topics 3 and 4 which read as follows:[6]

> 3. FACTS relating to the evolution of the composition and formulations of EFFEXOR XR and the development thereof from June 1990 through July 2002. (This should be interpreted to include modification to the formulations during that period, methods of manufacturing, when and where they were developed, who developed them, and what materials and methods were used to develop them). To limit this request further we are acceding to Wyeth's request to not include toxicology, quality control, animal testing, purchasing and qualification of raw materials, or packaging.
>
> 4. FACTS relating to the *in vitro* and *in vivo* release and bioavailability profiles of EFFEXOR XR from June 1990 through July 2002, including target profiles, when and where those profiles were first achieved, who was involved and oversaw this achievement, and what materials and methods were used to test and achieve them, modifications to those release profiles, and difficulties in consistently replicating those profiles. (EFFEXOR XR should be interpreted to include formulations prepared in the

[6] These two Topics are essentially of the same scope, respectively, as overbroad Topics 3 and 7 of Impax's First Amended Notice.

development of WYETH'S commercial EFFEXOR XR™, but excluding hydrogel tablets and gelucire capsules.)

On their face, the plain language of these topics demonstrates their overbreadth. Topic 3, for example, seeks testimony regarding a variety of unspecified activities that could be interpreted as "relating to the evolution of the composition and formulations of EFFEXOR XR and the development thereof" spanning a 12-year period from 1990 to 2002.[7]

Although Impax indicates that certain activities are not within the scope of the topic (toxicology, quality control, animal testing, purchasing and qualification of raw materials, and packaging), there are still countless activities that do potentially fall within its scope.[8] As Wyeth indicated to Impax, this topic still embraces dissolution studies, stability studies, scale-up for commercial production, bioavailability studies, clinical trials on safety and efficacy, clinical batch manufacturing, commercial manufacturing, and labeling. [Ex. 8, March 13, 2007 letter from Rudolph to Kassabian at 1-2]. It also embraces testing and use of Effexor XR for the treatment of depression, the treatment of social anxiety disorder, the treatment of generalized anxiety disorder, the treatment of panic disorder, and all regulatory matters pertaining to Effexor XR, including all filings and correspondence with the FDA. [*Id.*]. Wyeth should not be left to guess as to which of these activities Impax seeks testimony, or the potential scores of individuals that could

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7 Moreover, Impax's notice is overbroad for the additional reason that it seeks testimony on activities that occurred after the 1996 filing date and, thus, are not relevant to the issue of "evolution of the composition and formulations of EFFEXOR XR."

8 Indeed, Impax's Second Amended Notice expressly states that the topic, like the other topics, "should be interpreted to include," but not limited to, certain activities.

be interpreted as having been "involved" in those activities over the 12-year period. Given the sheer volume of activities and number of people potentially involved, there can be no serious doubt that Wyeth would be unduly burdened in trying to properly educate witnesses to respond to such a broad and ambiguous topic. And Impax certainly has not demonstrated how its purported need for such discovery outweighs the burden it places on Wyeth. Impax plainly has access to such discovery from other means. For example, Wyeth has already produced to Impax the deposition testimony of the named inventors of the patents-in-suit from the prior Teva case, and Impax can notice these same inventors in this case.

Topic 4 similarly seeks testimony "relating to the *in vitro* and *in vivo* release and bioavailability profiles of EFFEXOR XR" spanning the 12-year period from 1990 to 2002. Again, as with Topic 3, there are many unspecified activities that could be interpreted as within the scope of this topic, and Wyeth is left to guess what Impax really seeks. On its face, this topic could be interpreted to embrace almost any activity conducted in connection with a number of Wyeth's clinical trials on Effexor XR. And as with Topic 2, there could be scores of employees that were "involved in" those activities and would thus fall within the scope of the topic, even though their involvement may have been only marginal. In short, Impax has failed to demonstrate how its need for such discovery outweighs the burden it places on Wyeth to prepare witnesses on such a broad and undefined topic, particularly given that Wyeth already has produced to Impax the Rule 30(b)(6) testimony from the prior Teva case regarding Wyeth's clinical trials on Effexor XR.

3. Impax's "General Topic III" Actually Consists Of *Four* Separate Topics That Are Each Overly Broad

Putting aside the improper argumentative nature of its "general topic III," the topic actually consists of Topics 5-8, which seek testimony regarding the compositions, development histories, and the *in vitro* and *in vivo* release profile histories from June 1990 through March 1996 for two other formulations: "hydrogel tablets" and "gelucire tablets."[9]

Again, despite Impax's disclaimer of certain activities, there are still many undefined activities, and a variety of methods and materials for each activity, that could be interpreted to relate to the "development" of the hydrogel and gelucire formulations over the 1990-1996 time-frame, and unspecified employees that may have been "involved in" those activities, even if only marginally so. Impax has failed to demonstrate how its need for such discovery outweighs the burden it places on Wyeth to prepare a witness on such undefined topics, particularly when combined with Impax's 28 other topics.

4. Impax's "General Topic IV" Actually Consists Of *Three* Separate Topics That Are Each Overly Broad

Impax's "general topic IV" is an improper argumentative "topic" that actually consists of Topics 9, 10 and 11.[10] Topic 9 seeks testimony "relating to the composition and intended use of" an Alza Oros formulation, and the "historical development thereof" during a 12-year time period spanning from June 1990 through July 2002. Similarly,

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[9] These topics are of essentially the same scope as Topics 4, 5, 8, and 9 of Impax's First Amended Notice.

[10] These Topics are of essentially the same scope as Topics 6, 10, and 11 of Impax's First Amended Notice.

Topic 10 seeks testimony "relating to the *in vitro* and/or *in vivo* release profiles" of any Wyeth formulation utilizing the Alza Oros technology. For many of the same reasons set forth above for Topics 3 and 4, Topics 9 and 10 are overly broad.[11]

Although Impax again excluded certain activities (*e.g.*, toxicology, quality control, etc.) from Topic 9, it nonetheless states that the topic should be "interpreted to include" (but is not limited to) "modification to the formulation during that period, methods of manufacturing, when those formulations were developed, where they were developed, who developed them, and what materials and methods were used to develop them." As with Topics 3 and 4 above, the "development" of the formulation could encompass many additional and unspecified activities, and involve many individuals, that may be of only marginal relevance.

Topic 9 also calls for Wyeth's contentions because it asked for testimony concerning the formulations' intended use and what they were expected to do, including: "the formulations' intended use by patients, whether the formulations were expected to

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[11] Impax's oft-repeated allegation that Wyeth has impeded discovery in connection with the Alza formulations is plainly not true. [Impax Br. at 9, n.4]. Wyeth has produced to Impax thousands of pages of documents relating to the Alza/Wyeth collaboration. Wyeth is in the process of responding to the narrowed interrogatory the Court specified at the March 2 hearing, which is due on April 2, 2007. To the extent there has been any delay in obtaining documents directly from Alza, that is because of Impax's unilateral decision to negotiate a protective order directly with Alza, without even informing Wyeth of those negotiations, much less seeking Wyeth's views on the terms of the draft protective order. Had Alza and Impax merely used the pre-existing Protective Order in this case, which has provisions for documents produced by third parties, the documents from Alza would have been produced long ago. In any event, Wyeth is attempting to resolve with Alza its disagreements on the proposed Alza protective order. If an agreement is not reached, Wyeth will file on April 3, 2007, its opposition to Impax's Motion to enter the Alza protective order, and will propose revisions to the protective order that was developed by Alza and Impax.

provide a therapeutic blood plasma concentration of VENLAFAXINE over a twenty four hour period with diminished incidences of nausea and emesis, whether the formulations were expected to eliminate the troughs and peaks of drug concentration in a patients blood plasma attending the therapeutic metabolism of plural daily doses of VENLAFAXINE...." As noted previously with respect to Topic 1, Rule 30(b)(6) testimony is not the proper discovery mechanism for ascertaining a party's contentions. *Heron*, 2006 WL 3703693 at *1; *McCormick-Morgan, Inc.*, 134 F.R.D. at 287; *McKesson Info Solutions LLC*, C.A. No. 04-01258 (SLR) (Tr. at 21).

Topic 10 is also overbroad in that it seeks testimony regarding virtually all aspects of clinical testing of any Alza Oros formulations and anyone "involved" in that testing. As with Topics 3 and 4 above, this topic literally encompass many unspecified activities, and potentially involves many individuals, regardless of their relevance to the issues in the litigation.

Topic 11 is overbroad in that it seeks testimony on any and all "studies, tests, trials, research, or experiments" conducted during the 12-year time period spanning from June 1990 to July 2002 that compares chemical properties of venlafaxine (and its salts) to another drug, propranolol (and its salts). This single topic embraces nearly any testing activity conducted on those two drugs or their salts during a 12-year period including development work (dissolution studies, stability studies) human trials (safety, bioavailability and efficacy studies), manufacturing studies (including clinical batch manufacturing and commercial scale-up manufacturing tests and studies). It would also require Wyeth to contact numerous individuals to determine their "knowledge" of any chemical property comparisons of those two drugs made during those years of activity.

This topic is virtually unbounded in scope and Impax fails to demonstrate how its need for such discovery outweighs the undue burden it places on Wyeth to prepare witnesses on such a broad and undefined topics. Indeed, U.S. Patent No. 4,138,475, referred to by Impax, describes the propranolol formulation and was considered by the U.S. Patent and Trademark Office during prosecution of the patents-in-suit. The Patent Office correctly concluded that the claims were patentable over the propranolol formulation.

5. Impax's "General Topic V" Actually Consists Of *Six* Topics, Four Of Which Are Overbroad, Seek Wyeth's Legal Contentions And/Or Seek Information Protected By The Attorney-Client Privilege

Impax's "general topic V" is yet another improper argumentative topic, and actually consists of Topics 12-17.[12]

First, Topics 16 and 17 seek Wyeth's legal contentions. These topics seek, respectively, testimony regarding "WYETH's knowledge and research prior to July 2002 demonstrating or refuting" two specific claim limitations: (1) that Wyeth's extended release formulations provided "a therapeutic blood plasma concentration of VENLAFAXINE over a twenty-four hour period with diminished incidences of nausea and emesis" or (2) that Wyeth's extended release formulations "eliminated the troughs and peaks of drug concentration in a patients blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine." Thus, on their face, these two topics embrace testimony regarding Wyeth's legal contentions regarding the meaning and

[12] Topics 12-15 are of essentially the same scope as Topics 29, 30, 31, and 32 of Impax's First Amended Notice, while Topics 16 and 17 of the Second Amended Notice are actually *broader* (and thus more burdensome to Wyeth) than Topics 13 and 14 of Impax's First Amended Notice because of the change in cut-off date.

support for those claims. As noted previously, Rule 30(b)(6) testimony is not the proper mechanism for discovering such legal contentions.

Indeed, with respect to the improved tolerability of the extended release formulation of venlafaxine compared to the immediate release formulation of venlafaxine, and the elimination of troughs and peaks of drug concentration in a patients blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine, Wyeth identified to Impax

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is needlessly duplicative, and unduly burdensome for Wyeth, to now have to prepare one or more designees to testify concerning the contents of the voluminous evidence that already has been produced and identified to Impax.

In addition, Topics 16 and 17 are unreasonably broad in that they would literally require a designee to identify every result of every study ever conducted by Wyeth on its extended release venlafaxine prior to July of 2002 (including many clinical trials), and then determine for every single test whether the results either support or refute the claim limitations at issue. Impax fails to demonstrate how its need for such discovery outweighs the undue burden it places on Wyeth to prepare a witness on such broad and undefined topics. Further, as noted previously, Wyeth has already produced documents and testimony from the Teva litigation including Rule 30(b)(6) testimony on Wyeth's clinical trials on extended release venlafaxine and the statistical basis for various

statements in the patents-in-suit that contain much of the information that Impax seeks in Topics 16 and 17.[13]

Topics 12 and 14 seek testimony on whether the named inventors or those that prosecuted the patents-in-suit were "aware" of two specific publications before or during the prosecution of the patents. These topics thus seek testimony on Wyeth's contentions and/or information that implicates communications protected by the attorney-client privilege. Therefore, the discovery sought is best obtained through a different discovery mechanism such as contention interrogatories. As noted, courts have denied Rule 30(b)(6) testimony on a party's legal contentions and/or when the "facts" are inextricably intertwined with communications protected by the attorney-client privilege. *McCormick-Morgan, Inc.*, 134 F.R.D. at 287; *Hercules Inc.*, 434 F. Supp. at 144.

6. Impax's "General Topic VI" Actually Consists Of *Eight* Topics Which Are Overbroad, Seek Wyeth's Legal Contentions, Seek Information Protected By The Attorney-Client Privilege, And/Or Seek Expert Testimony

Impax's "general topic VI" actually consists of Topics 18-25,[14] all of which are objectionable for a variety of reasons.

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[13] Wyeth will address at an appropriate time Impax's baseless allegations of inequitable conduct. Suffice it to say that the expert reports from the Teva litigation that have been produced to Impax, as well as other documents Wyeth has produced, clearly show that Effexor XR, the extended release version of venlafaxine, results in reduced nausea and vomiting as compared to Effexor, the immediate release version of venlafaxine. Indeed, the improved tolerability of Effexor XR over Effexor made Effexor XR far more successful than Effexor. Although Impax notes that the sales of Effexor XR were about $2.6 billion in 2006 [Impax Br., D.I. 113 at 1, n.1], it fails to mention that the sales of Effexor plateaued several years after launch at about $225 million per year.

[14] These Topics are of essentially the same scope (or in the case of Topic 24, *broader*) as Topics 11, 12, 22, 23, 28, 24, 33 and 34, respectively, of Impax's First Amended Notice.

First, Topics 20-25 are overbroad and lack reasonable particularity. Topics 20-22 seek testimony on "the drafting of, the preparation of, and the intended meaning of" certain passages in the patents-in-suit or in the prosecution history. However, to the extent that Impax is seeking the intended meaning of the passages from the perspective of the author, such meaning is irrelevant as the only relevant inquiry is what those passages mean to *one of ordinary skill in the art*. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 985-86 (Fed. Cir. 1995)(*en banc*). Similarly, Topics 18-22 improperly seek expert testimony on the support for, and in some cases the intended meaning of, specific portions of the patents-in-suit or statements made during prosecution of the patents before the U.S. Patent and Trademark Office.

Moreover, as the general heading makes clear, Impax also seeks the facts "required to understand" these portions of the patent specification and prosecution history. Clearly, whether the topic seeks the "intended meaning" of passages from a patent, or facts "required to understand" those passages, Impax is seeking expert testimony regarding the meaning of terms and phrases to one of ordinary skill in the art at the time of the invention. This is a topic for expert discovery, not a Rule 30(b)(6) deposition.

Similarly, Topics 20-22 also are improper to the extent they seek Wyeth's legal contentions regarding the intended meaning of certain passages in the patents-in-suit. As noted previously, this Court and others have ruled that Rule 30(b)(6) testimony is not the proper discovery mechanism to discover a party's legal contentions regarding such meaning. *See In re Linerboard Antitrust Litigation*, 237 F.R.D. 373, (E.D. Pa. 2006) (denying motion to compel Rule 30(b)(6) testimony regarding meaning of phrases in a

White Paper because of inherent privilege and work product issues, and because moving party had "extensive non-privileged sources of the same information."); *United States v. District Council of New York City*, No. 90 CIV. 5722 (CSH), 1992 WL 208284 at *15 (S.D.N.Y. Aug. 18, 1992)(denying Rule 30(b)(6) testimony because the government need not "marshal all its factual proof and then provide it to Agent Worsham so that she could respond to what are essentially a form of contention interrogatories."). Moreover, Topics 20-22 also improperly impinge upon attorney-client privilege because they seek testimony on the drafting and preparation of the cited passages from the patents-in-suit and prosecution history. The attorney-client privilege extends to technical information communicated between attorney and client for the purpose of securing and rendering legal advice. *SmithKline Beecham Corp. v. Apotex Corp.*, 232 F.R.D. 467, 480 (E.D. Pa. 2005); *Conner Peripherals, Inc. v. Western Digital Corp.*, No. C93-20117 RMW/EAI, 1993 WL 726815 at *3 (N.D. Cal. June 8, 1993). Because this requested discovery is so intertwined with issues of attorney-client privilege, it is best conducted through alternative discovery mechanisms.

Moreover, although Impax seeks the support for a certain passage in the patents-in-suit in Topic 20, Wyeth already responded to contention interrogatories on this subject, and has identified by production number the pertinent documents. [15] Requiring Wyeth to prepare

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[15] Magistrate Judge Shwartz rejected Impax's erroneous interpretation of the passage in the patents-in-suit regarding clinical trials [Impax Br., D.I. 113 at 12] in the Teva case.

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a Rule 30(b)(6) witness to address the voluminous documentary support which already has been provided and identified to Impax is not a proper application of Rule 30(b)(6).

Topics 23-25, which seek testimony about Wyeth's patent practices and policies, also seek testimony on information protected by the attorney-client privilege and/or work product immunity. Topic 23 reads:

> WYETH's practices and policies from June 1990 through July 2002 with respect to the prosecution of U.S. Patent applications. (This includes the preparation of invention disclosures, evaluation of inventions, performing prior art searches, preparing patent applications, informing inventors of their duty of candor to the Patent Office, gathering and submitting prior art during the course of patent prosecution, evaluation of U.S. Patent and Trademark Office actions and examiner amendments, drafting and review of responses to Office actions, decisions to file provisional, continuation or continuation-in-part applications, and decisions to abandon applications.)

The preparation and prosecution of a patent are the "hallmark activities of a lawyer," and this Court has recognized that communications between a client and a patent attorney for the purpose of securing legal advice in connection with those proceedings is protected by the attorney-client privilege. *Hercules.*, 434 F. Supp. at 147 (citing *Sperry v. State of Florida*, 373 U.S. 379 (1963). The testimony that Impax seeks would reveal confidential communications made by the client to Wyeth attorneys for the purpose of seeking legal services, and is immune from discovery. Similarly, the mental impressions of the attorneys that drafted and prosecuted the patent applications is also protected to the extent that they were based on privileged communications. *Advanced Cardiovascular Sys., Inc. v. C.R. Bard, Inc.*, 1441 F.R.D. 372, 378-79 (N.D. Cal. 1992)(patent attorney's understanding of terms in a patent held not discoverable to the extent it was based on privileged communications with inventors).

Topic 24 seeks testimony regarding Wyeth's procedures for collecting and maintaining documents, including the measures that "are or were taken to ensure that all relevant documents are or were collected" in response to Impax's document requests, as well as those propounded to Wyeth in the Teva litigation. The Topic also specifically seeks "without limitation how the DOCUMENTS are organized." Here, because Impax is seeking discovery as to how Wyeth collected and maintained its documents in response to two litigations, and the manner in which Wyeth organizes its documents, it would reveal information protected by the attorney-client privilege and/or work product immunity. Impax can obtain this information through other discovery mechanisms -- such as an interrogatory -- which will avoid any privilege or work product concerns.

Topic 25, which implicitly seeks Wyeth's contentions in two paragraphs of its Reply to Impax's Counterclaims. But Wyeth already provided its support for these contentions in response to contention interrogatories.

REDACTED Moreover, it is improper to seek such contentions through a Rule 30(b)(6) deposition. To the extent that Wyeth made affirmative statements or denials in a pleading, there are more appropriate discovery mechanisms to obtain such discovery, such as contention interrogatories. And, as noted, Wyeth has provided answers to such contention interrogatories.

Further, Wyeth has already produced to Impax Rule 30(b)(6) testimony given in the prior Teva litigation regarding Wyeth's clinical trials and support for statements in the patents-in-suit. As such, Impax has much of the information it seeks from these topics.

7. Impax's "General Topic VII" Actually Consists Of *Four* Sub-Topics Which Are Overbroad, Seek Wyeth's Legal Contentions And/Or Seek Expert Testimony

Impax's "general topic VII," which is improperly argumentative, consists of Topic 26 which, in turn, contains four sub-parts, each of which seek testimony on facts "evidencing" various portions of Wyeth's NDA No. 20-699 on extended release venlafaxine.[16] As set forth below, each of these subparts is overly broad and seeks Wyeth's legal contentions and/or expert testimony.

Subpart (a) seeks facts "evidencing" the Integrated Safety Summary of Wyeth's NDA. This sub-part alone is overbroad in that the Integrated Safety Summary is a summary document submitted to the FDA that collates and analyzes data from all of Wyeth's clinical studies for extended release venlafaxine hydrochloride that were conducted or commenced as of its submission to the FDA. The Integrated Safety Summary covers, *inter alia*,

[16] This Topic is actually *broader* than the corresponding Topic 15 of Impax's First Amended Notice as it now seeks "facts evidencing" various parts of Wyeth's NDA, rather than just the parts themselves.

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The burden on Wyeth to prepare a witness ~~to testify on every~~ aspect of just this one document alone is enormous.

Similarly, sub-part (b) seeks facts "evidencing" the Summary of Human and Pharmacokinetics and Bioavailability, which is also a portion of the Wyeth's NDA and is also a summary document based on Wyeth's clinical studies, but focused on pharmacokinetics, bioavailability, and drug formulation. This document includes subjects such as

Again, to prepare a witness to cover just this material alone would be an enormous burden on Wyeth.

In short, under the plain language of these sub-parts, Impax is apparently expecting Wyeth to prepare a witness to testify regarding any and all facts having any relation whatsoever to Wyeth's clinical studies. But Wyeth's NDA, a significant portion of which relates to human testing and clinical experience, spans over 85,000 pages. Impax has not demonstrated how its need for such discovery outweighs the undue burden it would place on Wyeth to prepare a witness on such a broad and undefined topic.

Finally, subparts (c) and (d) relate to a human trial which already has been produced to Impax. Impax seeks Wyeth's contentions as to the support for statements in

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the trial report. But Impax has the report, and a Rule 30(b)(6) deposition is not a proper mechanism to obtain Wyeth's contentions about it.

8. Impax's "General Topic VIII" Actually Consists Of *Six* Topics Which Are Overbroad, And/Or Seek Expert Testimony

Impax's "general topic VIII," which like Impax's other "general topic" headings is improperly argumentative, actually consists of Topics 27-32, each of which are overbroad, and/or seeks expert testimony.[17] Topic 27 reads:

> For the years 1997 through the second quarter of 2006, causes in any fluctuations of, and strategies to maintain or increase, the market share of Effexor XR in the United States.

Topic 27 is overly broad in that it seeks testimony on "causes in any fluctuations" of market share over a 9-year period. Impax does not define what it means by a "fluctuation" and thus there is simply no way for Wyeth to know what quantum of change in market share Impax believes constitutes a "fluctuation." Moreover, "causes" of market share fluctuations are more properly the realm of contention or expert discovery. Wyeth already has responded to contention interrogatories on commercial success and has provided an expert report on this issue from the Teva litigation. [*See* Ex. 9, Wyeth Response to Interrogatory No. 25 served on October 10, 2006].

Topic 28 is overbroad in that it seeks testimony on advertising budgets which are irrelevant. Wyeth has already produced its advertising expenses for Effexor XR which detail the amounts Wyeth actually spent on advertising, rather than speculative amounts of budgets. Moreover, to the extent that Topic 28 seeks testimony on the "effectiveness"

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17 With the exception of Topics 29 and 31, these Topics are of essentially the same scope as Topics 17, 19, 20, and 16 of Impax's First Amended Notice.

of advertising, such information is again more properly in the realm of contention or expert testimony.

Topic 29, which seeks testimony on "strategies to shift or switch the subscription and/or the consumption" of Effexor XR to another drug product that has yet to be launched and having an entirely different active ingredient is totally irrelevant to the issue of the commercial success of Effexor XR.

Topic 30 seeks the content and effectiveness of advertising for immediate release Effexor, which is not even the subject of this litigation. Moreover, testimony on the "effectiveness" of advertising and promotional efforts is overly broad, unduly burdensome, and more properly the subject of expert testimony.

Topic 31 is overly broad in that it seeks testimony on all correspondence with any advertising agencies "involved in advertising" Effexor XR and Effexor regardless of whether it is relevant to any issue in this case. As such, on its face, this one topic could embrace communications such as invoices, logistics of any advertising efforts, contracts, proposals, confidentiality agreements, and other irrelevant issues.

Topic 32 seeks testimony on revenues, expenses and profitability from the sale of Effexor XR in the United States including sales projections, actual sales, market share and profit margins. This topic is overly broad and unduly burdensome. Wyeth has already produced documents showings its actual sales and market share. Moreover, sales projections and profit margins are simply irrelevant to any issue in this case.

C. Impax Ignored The Court's March 2, 2007 Ruling That Its First Amended Notice Topics Were Overbroad In Preparing Nearly Identical Or Broader Topics For Its Second Amended Notice

Preparing witnesses to provide testimony on all of the above information embraced by Impax's 32 topics in one deposition would be nearly impossible. The amount and diversity of subjects covered by the Second Amended Notice stretches Impax's proposed discovery beyond reasonable bounds. Yet Impax doggedly persists in clinging to its already-rejected argument that Fed.R.Civ.P. 26 governs the permissible scope of a Rule 30(b)(6) deposition. But as Wyeth set forth previously, Rule 26 does not and cannot eviscerate the requirement of "reasonable particularity" of Rule 30(b)(6). Impax's reliance on the factors set forth in *Hagemeyer N. Am., Inc. v. Gateway Data Sci. Corp.*, 222 F.R.D. 594 (E.D. Wis. 2004) is misplaced because that case does not even involve Rule 30(b)(6), much less address the reasonable particularity requirement.

Moreover, the factors that Impax cites do not support its position. Impax argues that a Rule 30(b)(6) deposition is needed because witnesses in the Teva litigation could not recall "key details." [Impax Br., D.I 113 at 15]. But as Wyeth explained, Impax has exaggerated these claims. [Wyeth's Reply Br., D.I. 97 at 5]. For example, Impax points to a snippet of

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but fails to explain how this is a "key detail." Moreover, such information is available from the laboratory notebooks Wyeth already produced.

Impax's repeated incantation that Wyeth has delayed and obfuscated discovery is simply incorrect. [Impax Br., D.I. 113 at 15]. Wyeth has timely produced over one million pages of documents, extensive expert, fact, and Rule 30(b)(6) deposition

testimony from the prior Teva case, and exhaustive responses to contention interrogatories in the present case.

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Impax's assertion that its massive Rule 30(b)(6) Notice is the "most efficient way to proceed with discovery" [Impax Br., D. I. 113 at 15] is simply an effort to shift the burden to Wyeth to prepare Impax's case. Given the extensive discovery that Wyeth already has provided to Impax, such burden shifting is entirely inappropriate and unsupportable.

Impax further suggests that because Effexor XR is so commercially successful, it is "too important to prevent full discovery of critical issues." [*Id.* at 15]. But it is Impax that has, until recently, opted not to seek deposition discovery other than its overbroad and improper Rule 30(b)(6) Notices. Moreover, Wyeth has provided full discovery to Impax, and Impax simply has chosen not to analyze the discovery it has been provided.

Impax argues that Wyeth has ample resources to locate a Rule 30(b)(6) designee as Wyeth was prepared to go to trial in the Teva case. [Impax Br. at 16]. As previously discussed, however, that Wyeth was prepared to go to trial in another case that did not contain all of the issues raised in Impax's Second Amended Notice does not reduce the

undue burden it would face in preparing multiple witnesses to testify for "four days" on Impax's overly broad 32 topics, that reach far beyond the factual and legal contours of the Teva case.

Lastly, the privilege issues previously raised by Wyeth in its Motion for a Protective Order were not, contrary to Impax's suggestion [Impax Br. at 17], decided by the Court at the March 2, 2007 hearing. They remain valid objections for the reasons previously discussed.

V. CONCLUSION

For the foregoing reasons, the Court should deny Impax's motion to compel deposition pursuant to Fed. R. Civ. P. 30(b)(6).

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CERTIFICATE OF SERVICE

I, Karen Jacobs Louden, hereby certify that on April 17, 2007, I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing(s) to the following:

Mary B. Matterer
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I also certify that copies were caused to be served on April 17, 2007 upon the following in the manner indicated:

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